

**U.S. Environmental Protection Agency**  
**Science Advisory Board/Scientific Advisory Panel**  
**Notification of Public Advisory Committee Meeting**  
**Open Meeting**

Pursuant to the Federal Advisory Committee Act, Public Law 92-463, notice is hereby given that a Joint Subcommittee of the Science Advisory Board (SAB) and the Scientific Advisory Panel (SAP) will meet on the dates and times described below. All times noted are Eastern Standard Time. The meeting is open to the public; however, due to limited space, seating will be on a first-come basis.

The Joint SAB/SAP Data from Testing on Human Subjects (DTHS) Subcommittee will meet on Thursday and Friday, December 10/11, 1998 at the Sheraton Crystal Hotel, 1800 Jefferson Davis Highway, Arlington VA 22202. The hotel telephone number is 703-486-1111. The meeting will begin at 8:30 am and end no later than 5:00 pm. This is the first meeting of this Subcommittee.

**Purpose of the Meeting:** This Joint Subcommittee was established to provide advice and comment to EPA on issues related to data derived from testing on human subjects and its use in pesticides decision making. In the midst of this effort, some specific issues have arisen regarding the testing of human subjects in support of pesticide registrations. Both scientific and (primarily)

ethical questions have been raised about the data, the manner in which they were developed, and the purpose to which they can or should be put. The Agency thus seeks advice from the SAB/SAP Joint Committee on a range of issues, especially. focusing on the practical questions confronting the Pesticide Program as it seeks to implement the Food Quality Protection Act. During this public meeting, the Subcommittee will address these scientific and ethical issues, including: a) the value of human studies; b) how to determine what constitutes an appropriate (scientifically and ethically) human study; c) the risks and benefits to subjects and society; d) applying principles to specific situations; e) identifying clearly out-of-bounds studies; and f) assessing and assuring compliance with appropriate standards. A copy of the formal Charge to the Subcommittee will be posted on the SAB Website (<http://www.epa.gov/sab>) on or about November 16.

At the public meeting, Agency staff will brief the Subcommittee on current activities involving human studies, as well as on issues/problems raised by these activities. In concert with these presentations, EPA will present background materials for the Subcommittee's information and consideration.

**Availability of Review Materials** Hard copies of EPA primary background documents for the meeting may be obtained by contacting: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; Office location: Room. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202; telephone:

(703) 305-5805.

**For Further Information:** Members of the public desiring additional information about the conduct of the public meeting itself should contact Mr. Samuel Rondberg, Co-Designated Federal Officer, DTHS Subcommittee, Science Advisory Board (1400), Room M3706, U.S. EPA, 401 M Street, SW, Washington, DC 20460; telephone/voice mail at (301)-812-2560; fax at (202) 260-7118; or via E-mail at: samuelr717@aol.com. A copy of the draft agenda will be available on the SAB Website (<http://www.epa.gov/sab>) or the SAP Website (<http://www.epa.gov/pesticides/SAP/>), or upon request from Ms. Wanda Fields, Management Assistant, Science Advisory Board at (202) 260-5510 or by FAX at (202) 260-7118 or via E-Mail at: [fields.wanda@epa.gov](mailto:fields.wanda@epa.gov). Anyone desiring additional information on the substantive issues to be addressed at this meeting should contact Mr. Larry C. Dorsey, Co-Designated Federal Officer for the Subcommittee, Environmental Protection Agency (7509C), 401 M St., SW, Washington, DC 20460. Mr. Dorsey may be contacted via telephone/voice mail at (703) 305-5369, or by E-Mail at: [dorsey.larry@epa.gov](mailto:dorsey.larry@epa.gov).

Members of the public who wish to make a brief oral presentation to the Subcommittee must contact Mr. Rondberg in writing (by letter, fax, or by E-Mail - see previously stated information) no later than 12 noon Eastern Time, Friday, November 27, 1998 in order to be included on the Agenda. These oral comments will be limited to five minutes per speaker or organization. The request should identify the name of the individual making the presentation, the organization (if any) they will represent, any requirements for audio visual equipment (e.g.,

overhead projector, 35 mm projector, chalkboard, etc), and include at least 35 copies of an outline of the issues to be addressed or of the presentation itself. By mail, submit written comments to: The Public Information and Records Integrity Branch (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person or by delivery service, bring comments to: Room 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, Virginia 22202.

Comments and data also may be submitted electronically by sending electronic mail (E-Mail) to: [opt-docket@epamail.epa.gov](mailto:opt-docket@epamail.epa.gov). Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data also will be accepted on disks in WordPerfect 8.0 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number "OPP- ". No Confidential Business Information (CBI) should be submitted through E-Mail. Electronic comments may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found under **Supplementary Information** below.

**Supplementary Information** The Agency encourages that written statements be submitted before the meeting to provide Panel Members time to consider and review the comments.

Information submitted as a comment in response to this notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI).

Information marked CBI will not be disclosed except in accordance with procedures set forth in 40 CFR Part 2. An edited copy of the comment that does not contain the CBI material must be submitted for inclusion in the public docket. Information not marked confidential will be included in the public docket. All comments and materials received will be made part of the public record and will be considered by the Panel.

A public record has been established for this notice (including comments and data submitted electronically) under docket number “OPP- “. A public version of this record, including printed versions of electronic comments, which does not include information claimed as CBI, will be available for inspection from 8:30 am to 4:00 pm, Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, Virginia 22202.

The official record for this notice, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the address in "**Availability of Review Materials**" earlier in this Notice.

Date

Donald G. Barnes, Ph.D

Staff Director,

Science Advisory Board

Billing Code: 6560-50-P